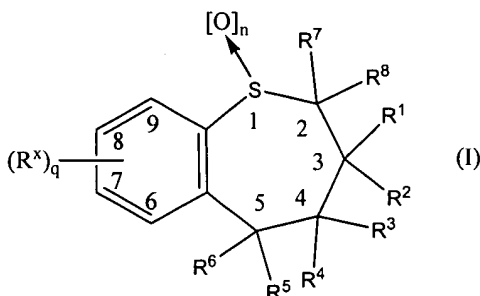


This Listing of Claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS

Claims 1-6 (canceled)

Claim 7 (new): A pharmaceutical composition comprising:  
a first amount of an ileal bile acid transport (IBAT) inhibitor of formula (I), a second amount of  
an HMG Co-A reductase inhibitor, and a pharmaceutically acceptable carrier,  
wherein said formula (I) is represented by:



wherein:

$q$  is an integer from 1 to 4;

$n$  is an integer from 0 to 2;

$\text{R}^1$  and  $\text{R}^2$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, haloalkyl, alkylaryl, arylalkyl, alkoxy, alkoxyalkyl, dialkylamino, alkylthio, (polyalkyl)aryl, and cycloalkyl,

wherein alkyl, alkenyl, alkynyl, haloalkyl, alkylaryl, arylalkyl, alkoxy, alkoxyalkyl, dialkylamino, alkylthio, (polyalkyl)aryl, and cycloalkyl optionally are substituted with one or more substituents selected from the group consisting of  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{R}^w\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{R}^{11}\text{A}^-$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ ,  $\text{CO}_2\text{R}^9$ , CN, halogen, oxo, and  $\text{CONR}^9\text{R}^{10}$ ,

wherein alkyl, alkenyl, alkynyl, alkylaryl, alkoxy, alkoxyalkyl, (polyalkyl)aryl, and cycloalkyl optionally have one or more carbons replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ , or phenylene,

wherein  $\text{R}^9$ ,  $\text{R}^{10}$ , and  $\text{R}^w$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, acyl, heterocycle, heteroaryl, ammoniumalkyl, arylalkyl, and alkylammoniumalkyl; or

$\text{R}^1$  and  $\text{R}^2$  taken together with the carbon to which they are attached form  $\text{C}_3\text{-C}_{10}$  cycloalkylidene;

$\text{R}^3$  and  $\text{R}^4$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, alkoxy, aryl, heterocycle, heteroaryl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{SR}^9$ ,  $\text{S(O)R}^9$ ,  $\text{SO}_2\text{R}^9$ , and  $\text{SO}_3\text{R}^9$ , wherein  $\text{R}^9$  and  $\text{R}^{10}$  are as defined above; or

$\text{R}^3$  and  $\text{R}^4$  together form  $=\text{O}$ ,  $=\text{NOR}^{11}$ ,  $=\text{S}$ ,  $=\text{NNR}^{11}\text{R}^{12}$ ,  $=\text{NR}^9$ , or  $=\text{CR}^{11}\text{R}^{12}$ , wherein  $\text{R}^{11}$  and  $\text{R}^{12}$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, arylalkyl, alkenylalkyl, alkynylalkyl, heterocycle, heteroaryl, carboxyalkyl, carboalkoxyalkyl, cycloalkyl, cyanoalkyl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{SR}^9$ ,  $\text{S(O)R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ ,  $\text{CO}_2\text{R}^9$ , CN, halogen, oxo, and  $\text{CONR}^9\text{R}^{10}$ , wherein  $\text{R}^9$  and  $\text{R}^{10}$  are as defined above, provided that both  $\text{R}^3$  and  $\text{R}^4$  cannot be OH,  $\text{NH}_2$ , or SH, or

$\text{R}^{11}$  and  $\text{R}^{12}$  together with the nitrogen or carbon atom to which they are attached form a cyclic ring;

$\text{R}^5$  and  $\text{R}^6$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $\text{SR}^9$ ,  $\text{S(O)R}^9$ ,  $\text{SO}_2\text{R}^9$ , and  $\text{SO}_3\text{R}^9$ ,

wherein alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl can be substituted with one or more substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl, halogen, oxo,  $\text{OR}^{13}$ ,

$\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S(O)R}^{13}$ ,  $\text{SO}_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ ,  $\text{CN}$ ,  $\text{OM}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{C(O)NR}^{13}\text{R}^{14}$ ,  $\text{C(O)OM}$ ,  $\text{COR}^{13}$ ,  $\text{P(O)R}^{13}\text{R}^{14}$ ,  $\text{P}^+\text{R}^{13}\text{R}^{14}\text{R}^{15}\text{A}^-$ ,  $\text{P(OR}^{13})\text{OR}^{14}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , and  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,

wherein:

$\text{A}^-$  is a pharmaceutically acceptable anion and  $\text{M}$  is a pharmaceutically acceptable cation, said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl can be further substituted with one or more substituents selected from the group consisting of  $\text{OR}^7$ ,  $\text{NR}^7\text{R}^8$ ,  $\text{SR}^7$ ,  $\text{S(O)R}^7$ ,  $\text{SO}_2\text{R}^7$ ,  $\text{SO}_3\text{R}^7$ ,  $\text{CO}_2\text{R}^7$ ,  $\text{CN}$ , oxo,  $\text{CONR}^7\text{R}^8$ ,  $\text{N}^+\text{R}^7\text{R}^8\text{R}^9\text{A}^-$ , alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $\text{P(O)R}^7\text{R}^8$ ,  $\text{P}^+\text{R}^7\text{R}^8\text{R}^9\text{A}^-$ , and  $\text{P(O)(OR}^7)\text{OR}^8$  and

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl, can optionally have one or more carbons replaced by O,  $\text{NR}^7$ ,  $\text{N}^+\text{R}^7\text{R}^8\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^7\text{A}^-$ ,  $\text{PR}^7$ ,  $\text{P(O)R}^7$ ,  $\text{P}^+\text{R}^7\text{R}^8\text{A}^-$ , or phenylene, and  $\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, polyalkyl, aryl, arylalkyl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl, and quaternary heteroarylalkyl,

wherein alkyl, alkenyl, alkynyl, arylalkyl, heterocycle, heteroaryl, and polyalkyl optionally have one or more carbons replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{PR}^9$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ ,  $\text{P(O)R}^9$ , phenylene, carbohydrate, amino acid, peptide, or polypeptide, and

$\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are optionally substituted with one or more groups selected from the group consisting of sulfoalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S(O)R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO(OR}^{16})\text{OR}^{17}$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{R}^{11}\text{A}^-$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ , and  $\text{C(O)OM}$ ,

wherein  $R^{16}$  and  $R^{17}$  are independently selected from the substituents constituting  $R^9$  and  $M$ ; or

$R^{14}$  and  $R^{15}$ , together with the nitrogen atom to which they are attached, form a cyclic ring;

$R^7$  and  $R^8$  are independently selected from the group consisting of hydrogen and alkyl; and

one or more  $R^x$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, polyalkyl, acyloxy, aryl, arylalkyl, halogen, haloalkyl, cycloalkyl, heterocycle, heteroaryl, polyether, quaternary heterocycle, quaternary heteroaryl,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $SR^{13}$ ,  $S(O)R^{13}$ ,  $S(O)_2R^{13}$ ,  $SO_3R^{13}$ ,  $S^+R^{13}R^{14}A^-$ ,  $NR^{13}OR^{14}$ ,  $NR^{13}NR^{14}R^{15}$ ,  $NO_2$ ,  $CO_2R^{13}$ ,  $CN$ ,  $OM$ ,  $SO_2OM$ ,  $SO_2NR^{13}R^{14}$ ,  $NR^{14}C(O)R^{13}$ ,  $C(O)NR^{13}R^{14}$ ,  $NR^{14}C(O)R^{13}$ ,  $C(O)OM$ ,  $COR^{13}$ ,  $OR^{18}$ ,  $S(O)_nNR^{18}$ ,  $NR^{13}R^{18}$ ,  $NR^{18}OR^{14}$ ,  $N^+R^9R^{11}R^{12}A^-$ ,  $P^+R^9R^{11}R^{12}A^-$ , amino acid, peptide, polypeptide, and carbohydrate,

wherein alkyl, alkenyl, alkynyl, cycloalkyl, aryl, polyalkyl, heterocycle, heteroaryl, acyloxy, arylalkyl, haloalkyl, polyether, quaternary heterocycle, and quaternary heteroaryl can be further substituted with  $OR^9$ ,  $NR^9R^{10}$ ,  $N^+R^9R^{11}R^{12}A^-$ ,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$ ,  $SO_3R^9$ , oxo,  $CO_2R^9$ ,  $CN$ , halogen,  $CONR^9R^{10}$ ,  $SO_2OM$ ,  $SO_2NR^9R^{10}$ ,  $PO(OR^{16})OR^{17}$ ,  $P^+R^9R^{11}R^{12}A^-$ ,  $S^+R^9R^{10}A^-$ , or  $C(O)M$ , and

wherein  $R^{18}$  is selected from the group consisting of acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl,

wherein acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl optionally are substituted with one or more substituents selected from the group consisting of  $OR^9$ ,  $NR^9R^{10}$ ,  $N^+R^9R^{11}R^{12}A^-$ ,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$ ,  $SO_3R^9$ , oxo,  $CO_2R^9$ ,  $CN$ , halogen,  $CONR^9R^{10}$ ,  $SO_3R^9$ ,  $SO_2OM$ ,  $SO_2NR^9R^{10}$ ,  $PO(OR^{16})OR^{17}$ , and  $C(O)OM$ ,

wherein in  $R^x$ , one or more carbons are optionally replaced by O,  $NR^{13}$ ,  $N^+R^{13}R^{14}A^-$ , S,  $SO$ ,  $SO_2$ ,  $S^+R^{13}A^-$ ,  $PR^{13}$ ,  $P(O)R^{13}$ ,  $P^+R^{13}R^{14}A^-$ , phenylene, amino acid, peptide, polypeptide, carbohydrate, polyether, or polyalkyl,

wherein in said polyalkyl, phenylene, amino acid, peptide, polypeptide, and carbohydrate, one or more carbons are optionally replaced by O,  $NR^9$ ,  $N^+R^9R^{10}A^-$ , S,  $SO$ ,  $SO_2$ ,  $S^+R^9A^-$ ,  $PR^9$ ,  $P^+R^9R^{10}A^-$ , or  $P(O)R^9$ ;

wherein quaternary heterocycle and quaternary heteroaryl are optionally substituted with one or more groups selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $SR^{13}$ ,  $S(O)R^{13}$ ,  $SO_2R^{13}$ ,  $SO_3R^{13}$ ,  $NR^{13}OR^{14}$ ,  $NR^{13}NR^{14}R^{15}$ ,  $NO_2$ ,  $CO_2R^{13}$ , CN, OM,  $SO_2OM$ ,  $SO_2NR^{13}R^{14}$ ,  $C(O)NR^{13}R^{14}$ ,  $C(O)OM$ ,  $COR^{13}$ ,  $P(O)R^{13}R^{14}$ ,  $P^+R^{13}R^{14}R^{15}A^-$ ,  $P(OR^{13})OR^{14}$ ,  $S^+R^{13}R^{14}A^-$ , and  $N^+R^9R^{11}R^{12}A^-$ ,

provided that both  $R^5$  and  $R^6$  cannot be hydrogen, OH, or SH, and  $R^5$  is OH,  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^7$ , and  $R^8$  cannot all be hydrogen;

provided that when  $R^5$  or  $R^6$  is phenyl, only one of  $R^1$  or  $R^2$  is H;

provided that when  $q=1$  and  $R^x$  is styryl, anilido, or anilinocarbonyl, only one of  $R^5$  or  $R^6$  is alkyl; or

a pharmaceutically acceptable salt, solvate, or prodrug thereof,

wherein said first amount is provided in a dosage range from about 0.3 mg/kg bodyweight/day to about 100 mg/kg bodyweight/day and

wherein said first and second amounts of said inhibitors together comprise an anti-hyperlipidemic condition effective amount.

Claim 8 (new): The pharmaceutical composition of claim 7 wherein said dosage range is from about 1 mg/kg bodyweight/day to about 50 mg/kg bodyweight/day.

Claim 9 (new): The pharmaceutical composition of claim 8 wherein said dosage range is from about 3 mg/kg bodyweight/day to about 10 mg/kg bodyweight/day.

Claim 10 (new): The pharmaceutical composition of claim 7 wherein said dosage range is subdivided into from about 2 to about 6 subdoses/day.

Claim 11 (new): The pharmaceutical composition of claim 7 wherein said HMG Co-A reductase inhibitor is selected from the group consisting of pitavastatin, rosuvastatin, mevastatin, and cerivastatin.

Claim 12 (new): The pharmaceutical composition of claim 7, wherein R<sup>5</sup> and R<sup>6</sup> are independently selected from the group consisting of H, aryl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl,

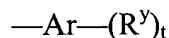
wherein said aryl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl can be substituted with one or more substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo, OR<sup>13</sup>, NR<sup>13</sup>R<sup>14</sup>, SR<sup>13</sup>, S(O)R<sup>13</sup>, SO<sub>2</sub>R<sup>13</sup>, SO<sub>3</sub>R<sup>13</sup>, NR<sup>13</sup>OR<sup>14</sup>, NR<sup>13</sup>NR<sup>14</sup>NR<sup>15</sup>, NO<sub>2</sub>, CO<sub>2</sub>R<sup>13</sup>, CN, OM, SO<sub>2</sub>OM, SO<sub>2</sub>NR<sup>13</sup>R<sup>14</sup>, C(O)NR<sup>13</sup>R<sup>14</sup>, C(O)OM, COR<sup>13</sup>, P(O)R<sup>13</sup>R<sup>14</sup>, P<sup>+</sup>R<sup>13</sup>R<sup>14</sup>R<sup>15</sup>A<sup>-</sup>, P(OR<sup>13</sup>)OR<sup>14</sup>, S<sup>+</sup>R<sup>13</sup>R<sup>14</sup>A<sup>-</sup>, and N<sup>+</sup>R<sup>9</sup>R<sup>11</sup>R<sup>12</sup>A<sup>-</sup>,

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can optionally have one or more carbons replaced by O, NR<sup>7</sup>, N<sup>+</sup>R<sup>7</sup>R<sup>8</sup>A<sup>-</sup>, S, SO, SO<sub>2</sub>, S<sup>-</sup>R<sup>7</sup>A<sup>-</sup>, PR<sup>7</sup>, P(O)R<sup>7</sup>, P<sup>+</sup>R<sup>7</sup>R<sup>8</sup>A<sup>-</sup>, or phenylene,

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can be further substituted with one or more substituents independently selected from the group consisting of OR<sup>7</sup>, NR<sup>7</sup>R<sup>8</sup>, SR<sup>7</sup>, S(O)R<sup>7</sup>, SO<sub>2</sub>R<sup>7</sup>, CO<sub>2</sub>R<sup>7</sup>, CN, oxo, CONR<sup>7</sup>R<sup>8</sup>, N<sup>+</sup>R<sup>7</sup>R<sup>8</sup>R<sup>9</sup>A<sup>-</sup>, alkyl, alkenyl, alkynyl, aryl, cycloalkyl,

heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $P(O)R^7R^8$ ,  $P^+R^7R^8R^9A^-$  and  $P(O)(OR^7)OR^8$ .

Claim 13 (new): The pharmaceutical composition of claim 12, wherein  $R^5$  or  $R^6$  has the formula:



wherein:

t is an integer from 0 to 5,

Ar is selected from the group consisting of phenyl, thiophenyl, pyridyl, piperazinyl, piperonyl, pyrrolyl, naphthyl, furanyl, anthracenyl, quinolinyl, isoquinolinyl, quinoxalinyl, imidazolyl, pyrazolyl, oxazolyl, isoxazolyl, pyrimidinyl, thiazolyl, triazolyl, isothiazolyl, indolyl, benzoimidazolyl, benzoxazolyl, benzothiazolyl, and benzoisothiazolyl; and

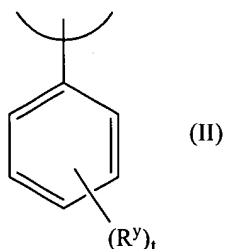
one or more  $R^y$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $OR^9$ ,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$  and  $SO_3R^9$ ,

wherein said alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, and heteroaryl can be substituted with one or more substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $SR^{13}$ ,  $S(O)R^{13}$ ,  $SO_2R^{13}$ ,  $SO_3R^{13}$ ,  $NR^{13}OR^{14}$ ,  $NR^{13}NR^{14}R^{15}$ ,  $NO_2$ ,  $CO_2R^{13}$ ,  $CN$ ,  $OM$ ,  $SO_2OM$ ,  $SO_2NR^{13}R^{14}$ ,  $C(O)NR^{13}R^{14}$ ,  $C(O)OM$ ,  $COR^{13}$ ,  $P(O)R^{13}R^{14}$ ,  $P^+R^{13}R^{14}R^{15}A^-$ ,  $P(OR^{13})OR^{14}$ ,  $S^+R^{13}R^{14}A^-$ , and  $N^+R^9R^{11}R^{12}A^-$ , wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can be further substituted with one or more substituents independently selected from the group consisting of  $OR^7$ ,  $NR^7R^8$ ,  $SR^7$ ,  $S(O)R^7$ ,  $SO_2R^7$ ,  $SO_3R^7$ ,  $CO_2R^7$ ,  $CN$ , oxo,  $CONR^7R^8$ ,  $N^+R^7R^8R^9A^-$ , alkyl, alkenyl, alkynyl, aryl, cycloalkyl,

heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $P(O)R^7R^8$ ,  $P^+R^7R^8R^9A^-$ , and  $P(O)(OR^7)OR^8$ ; and

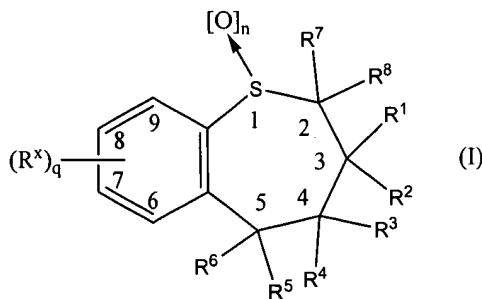
wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can optionally have one or more carbons replaced by O,  $NR^7$ ,  $N^+R^7R^8A^-$ , S,  $SO$ ,  $SO_2$ ,  $S^-R^7A^-$ ,  $PR^7$ ,  $P(O)R^7$ ,  $P^+R^7R^8A^-$ , or phenylene.

Claim 14 (new): The pharmaceutical composition of claim 13 wherein  $R^5$  or  $R^6$  has the formula (II):



Claim 15 (new): A combination therapy method for the treatment or prophylaxis of a hyperlipidemic condition in a patient in need thereof, said method comprising administering to said patient a pharmaceutical composition comprising a first amount of an ileal bile acid transport (IBAT) inhibitor of formula (I), a second amount of an HMG Co-A reductase inhibitor, and a pharmaceutically acceptable carrier,

wherein said formula (I) is represented by:





wherein:

q is an integer from 1 to 4;

n is an integer from 0 to 2;

$R^1$  and  $R^2$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, haloalkyl, alkylaryl, arylalkyl, alkoxy, alkoxyalkyl, dialkylamino, alkylthio, (polyalkyl)aryl, and cycloalkyl,

wherein alkyl, alkenyl, alkynyl, haloalkyl, alkylaryl, arylalkyl, alkoxy, alkoxyalkyl, dialkylamino, alkylthio, (polyalkyl)aryl, and cycloalkyl optionally are substituted with one or more substituents selected from the group consisting of  $OR^9$ ,  $NR^9R^{10}$ ,  $N^+R^9R^{10}R^wA^-$ ,  $SR^9$ ,  $S^+R^9R^{10}A^-$ ,  $P^+R^9R^{10}R^{11}A^-$ ,  $S(O)R^9$ ,  $SO_2R^9$ ,  $SO_3R^9$ ,  $CO_2R^9$ , CN, halogen, oxo, and  $CONR^9R^{10}$ ,

wherein alkyl, alkenyl, alkynyl, alkylaryl, alkoxy, alkoxyalkyl, (polyalkyl)aryl, and cycloalkyl optionally have one or more carbons replaced by O,  $NR^9$ ,  $N^+R^9R^{10}A^-$ , S, SO,  $SO_2$ ,  $S^+R^9A^-$ ,  $P^+R^9R^{10}A^-$ , or phenylene,

wherein  $R^9$ ,  $R^{10}$ , and  $R^w$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, acyl, heterocycle, heteroaryl, ammoniumalkyl, arylalkyl, and alkylammoniumalkyl; or

$R^1$  and  $R^2$  taken together with the carbon to which they are attached form  $C_3$ - $C_{10}$  cycloalkylidene;

$R^3$  and  $R^4$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, acyloxy, aryl, heterocycle, heteroaryl,  $OR^9$ ,  $NR^9R^{10}$ ,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$ , and  $SO_3R^9$ , wherein  $R^9$  and  $R^{10}$  are as defined above; or

$R^3$  and  $R^4$  together form  $=O$ ,  $=NOR^{11}$ ,  $=S$ ,  $=NNR^{11}R^{12}$ ,  $=NR^9$ , or  $=CR^{11}R^{12}$ , wherein  $R^{11}$  and  $R^{12}$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, arylalkyl, alkenylalkyl, alkynylalkyl, heterocycle, heteroaryl, carboxyalkyl, carboalkoxyalkyl, cycloalkyl, cyanoalkyl,  $OR^9$ ,  $NR^9R^{10}$ ,  $SR^9$ ,  $S(O)R^9$ ,

$\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ ,  $\text{CO}_2\text{R}^9$ , CN, halogen, oxo, and  $\text{CONR}^9\text{R}^{10}$ , wherein  $\text{R}^9$  and  $\text{R}^{10}$  are as defined above, provided that both  $\text{R}^3$  and  $\text{R}^4$  cannot be OH,  $\text{NH}_2$ , or SH, or  $\text{R}^{11}$  and  $\text{R}^{12}$  together with the nitrogen or carbon atom to which they are attached form a cyclic ring;

$\text{R}^5$  and  $\text{R}^6$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $\text{SR}^9$ ,  $\text{S(O)R}^9$ ,  $\text{SO}_2\text{R}^9$ , and  $\text{SO}_3\text{R}^9$ ,

wherein alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl can be substituted with one or more substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl, halogen, oxo,  $\text{OR}^{13}$ ,  $\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S(O)R}^{13}$ ,  $\text{SO}_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ , CN, OM,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{C(O)NR}^{13}\text{R}^{14}$ ,  $\text{C(O)OM}$ ,  $\text{COR}^{13}$ ,  $\text{P(O)R}^{13}\text{R}^{14}$ ,  $\text{P}^+\text{R}^{13}\text{R}^{14}\text{R}^{15}\text{A}^-$ ,  $\text{P(OR}^{13})\text{OR}^{14}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , and  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,

wherein:

$\text{A}^-$  is a pharmaceutically acceptable anion and M is a pharmaceutically acceptable cation, said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl can be further substituted with one or more substituents selected from the group consisting of  $\text{OR}^7$ ,  $\text{NR}^7\text{R}^8$ ,  $\text{SR}^7$ ,  $\text{S(O)R}^7$ ,  $\text{SO}_2\text{R}^7$ ,  $\text{SO}_3\text{R}^7$ ,  $\text{CO}_2\text{R}^7$ , CN, oxo,  $\text{CONR}^7\text{R}^8$ ,  $\text{N}^+\text{R}^7\text{R}^8\text{R}^9\text{A}^-$ , alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $\text{P(O)R}^7\text{R}^8$ ,  $\text{P}^+\text{R}^7\text{R}^8\text{R}^9\text{A}^-$ , and  $\text{P(O)(OR}^7)\text{OR}^8$  and

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl, can optionally have one or more carbons replaced by O,  $\text{NR}^7$ ,  $\text{N}^+\text{R}^7\text{R}^8\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^7\text{A}^-$ ,  $\text{PR}^7$ ,  $\text{P(O)R}^7$ ,  $\text{P}^+\text{R}^7\text{R}^8\text{A}^-$ , or phenylene, and  $\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are independently selected from the group consisting of hydrogen, alkyl,

alkenyl, alkynyl, polyalkyl, aryl, arylalkyl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl, and quaternary heteroarylalkyl, wherein alkyl, alkenyl, alkynyl, arylalkyl, heterocycle, heteroaryl, and polyalkyl optionally have one or more carbons replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{PR}^9$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ ,  $\text{P}(\text{O})\text{R}^9$ , phenylene, carbohydrate, amino acid, peptide, or polypeptide, and  $\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are optionally substituted with one or more groups selected from the group consisting of sulfoalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO}(\text{OR}^{16})\text{OR}^{17}$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{R}^{11}\text{A}^-$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ , and  $\text{C}(\text{O})\text{OM}$ , wherein  $\text{R}^{16}$  and  $\text{R}^{17}$  are independently selected from the substituents constituting  $\text{R}^9$  and M; or  $\text{R}^{14}$  and  $\text{R}^{15}$ , together with the nitrogen atom to which they are attached, form a cyclic ring;  $\text{R}^7$  and  $\text{R}^8$  are independently selected from the group consisting of hydrogen and alkyl; and one or more  $\text{R}^x$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, polyalkyl, acyloxy, aryl, arylalkyl, halogen, haloalkyl, cycloalkyl, heterocycle, heteroaryl, polyether, quaternary heterocycle, quaternary heteroaryl,  $\text{OR}^{13}$ ,  $\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S}(\text{O})\text{R}^{13}$ ,  $\text{S}(\text{O})_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ , CN, OM,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{NR}^{14}\text{C}(\text{O})\text{R}^{13}$ ,  $\text{C}(\text{O})\text{NR}^{13}\text{R}^{14}$ ,  $\text{NR}^{14}\text{C}(\text{O})\text{R}^{13}$ ,  $\text{C}(\text{O})\text{OM}$ ,  $\text{COR}^{13}$ ,  $\text{OR}^{18}$ ,  $\text{S}(\text{O})_n\text{NR}^{18}$ ,  $\text{NR}^{13}\text{R}^{18}$ ,  $\text{NR}^{18}\text{OR}^{14}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{P}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ , amino acid, peptide, polypeptide, and carbohydrate, wherein alkyl, alkenyl, alkynyl, cycloalkyl, aryl, polyalkyl, heterocycle, heteroaryl, acyloxy, arylalkyl, haloalkyl, polyether, quaternary heterocycle, and quaternary

heteroaryl can be further substituted with  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S(O)}\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO(OR}^{16})\text{OR}^{17}$ ,  $\text{P}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ , or  $\text{C(O)M}$ , and

wherein  $\text{R}^{18}$  is selected from the group consisting of acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl,

wherein acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl optionally are substituted with one or more substituents selected from the group consisting of  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S(O)}\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_3\text{R}^9$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO(OR}^{16})\text{OR}^{17}$ , and  $\text{C(O)OM}$ ,

wherein in  $\text{R}^x$ , one or more carbons are optionally replaced by O,  $\text{NR}^{13}$ ,  $\text{N}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^{13}\text{A}^-$ ,  $\text{PR}^{13}$ ,  $\text{P(O)R}^{13}$ ,  $\text{P}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , phenylene, amino acid, peptide, polypeptide, carbohydrate, polyether, or polyalkyl,

wherein in said polyalkyl, phenylene, amino acid, peptide, polypeptide, and carbohydrate, one or more carbons are optionally replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{PR}^9$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ , or  $\text{P(O)R}^9$ ;

wherein quaternary heterocycle and quaternary heteroaryl are optionally substituted with one or more groups selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo,  $\text{OR}^{13}$ ,  $\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S(O)R}^{13}$ ,  $\text{SO}_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ , CN, OM,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{C(O)NR}^{13}\text{R}^{14}$ ,  $\text{C(O)OM}$ ,  $\text{COR}^{13}$ ,  $\text{P(O)R}^{13}\text{R}^{14}$ ,  $\text{P}^+\text{R}^{13}\text{R}^{14}\text{R}^{15}\text{A}^-$ ,  $\text{P(OR}^{13})\text{OR}^{14}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , and  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,

provided that both  $\text{R}^5$  and  $\text{R}^6$  cannot be hydrogen, OH, or SH, and  $\text{R}^5$  is OH,  $\text{R}^1$ ,  $\text{R}^2$ ,  $\text{R}^3$ ,  $\text{R}^4$ ,  $\text{R}^7$ , and  $\text{R}^8$  cannot all be hydrogen;

provided that when  $\text{R}^5$  or  $\text{R}^6$  is phenyl, only one of  $\text{R}^1$  or  $\text{R}^2$  is H;

provided that when  $q=1$  and  $R^x$  is styryl, anilido, or anilinocarbonyl, only one of  $R^5$  or  $R^6$  is alkyl; or  
a pharmaceutically acceptable salt, solvate, or prodrug thereof,  
wherein said first amount is provided in a dosage range from about 0.3 mg/kg bodyweight/day to about 100 mg/kg bodyweight/day and  
wherein said first and second amounts of said inhibitors together comprise an anti-hyperlipidemic condition effective amount.

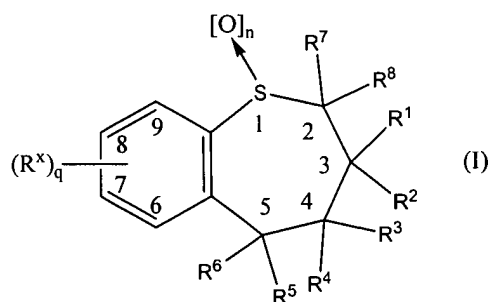
Claim 16 (new): The method of claim 15 wherein said dosage range is from about 1 mg/kg bodyweight/day to about 50 mg/kg bodyweight/day.

Claim 17 (new): The method of claim 16 wherein said dosage range is from about 3 mg/kg bodyweight/day to about 10 mg/kg bodyweight/day.

Claim 18 (new): The method of claim 15 wherein said dosage range is subdivided into from about 2 to about 6 subdoses/day.

Claim 19 (new): The composition of claim 15 wherein said HMG Co-A reductase inhibitor is selected from the group consisting of pitavastatin, rosuvastatin, mevastatin, and cerivastatin.

Claim 20 (new): An oral pharmaceutical composition comprising:  
a first amount of an ileal bile acid transport (IBAT) inhibitor of formula (I), a second amount of an HMG Co-A reductase inhibitor, and a pharmaceutically acceptable carrier,  
wherein said formula (I) is represented by:



wherein:

$q$  is an integer from 1 to 4;

$n$  is an integer from 0 to 2;

$R^1$  and  $R^2$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, haloalkyl, alkylaryl, arylalkyl, alkoxy, alkoxyalkyl, dialkylamino, alkylthio, (polyalkyl)aryl, and cycloalkyl,

wherein alkyl, alkenyl, alkynyl, haloalkyl, alkylaryl, arylalkyl, alkoxy, alkoxyalkyl, dialkylamino, alkylthio, (polyalkyl)aryl, and cycloalkyl optionally are substituted with one or more substituents selected from the group consisting of  $OR^9$ ,  $NR^9R^{10}$ ,  $N^+R^9R^{10}R^wA^-$ ,  $SR^9$ ,  $S^+R^9R^{10}A^-$ ,  $P^+R^9R^{10}R^{11}A^-$ ,  $S(O)R^9$ ,  $SO_2R^9$ ,  $SO_3R^9$ ,  $CO_2R^9$ , CN, halogen, oxo, and  $CONR^9R^{10}$ ,

wherein alkyl, alkenyl, alkynyl, alkylaryl, alkoxy, alkoxyalkyl, (polyalkyl)aryl, and cycloalkyl optionally have one or more carbons replaced by O,  $NR^9$ ,  $N^+R^9R^{10}A^-$ , S, SO,  $SO_2$ ,  $S^+R^9A^-$ ,  $P^+R^9R^{10}A^-$ , or phenylene,

wherein  $R^9$ ,  $R^{10}$ , and  $R^w$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, acyl, heterocycle, heteroaryl, ammoniumalkyl, arylalkyl, and alkylammoniumalkyl; or

$R^1$  and  $R^2$  taken together with the carbon to which they are attached form C<sub>3</sub>-C<sub>10</sub> cycloalkylidene;

$R^3$  and  $R^4$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, alkoxy, aryl, heterocycle, heteroaryl,  $OR^9$ ,  $NR^9R^{10}$ ,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$ , and  $SO_3R^9$ , wherein  $R^9$  and  $R^{10}$  are as defined above; or

$R^3$  and  $R^4$  together form  $=O$ ,  $=NOR^{11}$ ,  $=S$ ,  $=NNR^{11}R^{12}$ ,  $=NR^9$ , or  $=CR^{11}R^{12}$ , wherein  $R^{11}$  and  $R^{12}$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, arylalkyl, alkenylalkyl, alkynylalkyl, heterocycle, heteroaryl, carboxyalkyl, carboalkoxyalkyl, cycloalkyl, cyanoalkyl,  $OR^9$ ,  $NR^9R^{10}$ ,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$ ,  $SO_3R^9$ ,  $CO_2R^9$ , CN, halogen, oxo, and  $CONR^9R^{10}$ , wherein  $R^9$  and  $R^{10}$  are as defined above, provided that both  $R^3$  and  $R^4$  cannot be OH,  $NH_2$ , or SH, or

$R^{11}$  and  $R^{12}$  together with the nitrogen or carbon atom to which they are attached form a cyclic ring;

$R^5$  and  $R^6$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$ , and  $SO_3R^9$ ,

wherein alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl can be substituted with one or more substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl, halogen, oxo,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $SR^{13}$ ,  $S(O)R^{13}$ ,  $SO_2R^{13}$ ,  $SO_3R^{13}$ ,  $NR^{13}OR^{14}$ ,  $NR^{13}NR^{14}R^{15}$ ,  $NO_2$ ,  $CO_2R^{13}$ , CN, OM,  $SO_2OM$ ,  $SO_2NR^{13}R^{14}$ ,  $C(O)NR^{13}R^{14}$ ,  $C(O)OM$ ,  $COR^{13}$ ,  $P(O)R^{13}R^{14}$ ,  $P^+R^{13}R^{14}R^{15}A^-$ ,  $P(OR^{13})OR^{14}$ ,  $S^+R^{13}R^{14}A^-$ , and  $N^+R^9R^{11}R^{12}A^-$ ,

wherein:

$A^-$  is a pharmaceutically acceptable anion and  $M$  is a pharmaceutically acceptable cation, said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl can be further substituted with one or more substituents selected from the group consisting of  $OR^7$ ,  $NR^7R^8$ ,  $SR^7$ ,  $S(O)R^7$ ,  $SO_2R^7$ ,  $SO_3R^7$ ,  $CO_2R^7$ , CN, oxo,  $CONR^7R^8$ ,  $N^+R^7R^8R^9A^-$ , alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $P(O)R^7R^8$ ,  $P^+R^7R^8R^9A^-$ , and  $P(O)(OR^7)OR^8$  and

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl, can optionally have one or more carbons replaced by O,  $\text{NR}^7$ ,  $\text{N}^+\text{R}^7\text{R}^8\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^7\text{A}^-$ ,  $\text{PR}^7$ ,  $\text{P}(\text{O})\text{R}^7$ ,  $\text{P}^+\text{R}^7\text{R}^8\text{A}^-$ , or phenylene, and  $\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, polyalkyl, aryl, arylalkyl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl, and quaternary heteroarylalkyl,

wherein alkyl, alkenyl, alkynyl, arylalkyl, heterocycle, heteroaryl, and polyalkyl optionally have one or more carbons replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{PR}^9$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ ,  $\text{P}(\text{O})\text{R}^9$ , phenylene, carbohydrate, amino acid, peptide, or polypeptide, and

$\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are optionally substituted with one or more groups selected from the group consisting of sulfoalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO}(\text{OR}^{16})\text{OR}^{17}$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{R}^{11}\text{A}^-$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ , and  $\text{C}(\text{O})\text{OM}$ ,

wherein  $\text{R}^{16}$  and  $\text{R}^{17}$  are independently selected from the substituents constituting  $\text{R}^9$  and M; or

$\text{R}^{14}$  and  $\text{R}^{15}$ , together with the nitrogen atom to which they are attached, form a cyclic ring;

$\text{R}^7$  and  $\text{R}^8$  are independently selected from the group consisting of hydrogen and alkyl; and

one or more  $\text{R}^x$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, polyalkyl, acyloxy, aryl, arylalkyl, halogen, haloalkyl, cycloalkyl, heterocycle, heteroaryl, polyether, quaternary heterocycle, quaternary heteroaryl,  $\text{OR}^{13}$ ,  $\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S}(\text{O})\text{R}^{13}$ ,  $\text{S}(\text{O})_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ , CN, OM,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{NR}^{14}\text{C}(\text{O})\text{R}^{13}$ ,  $\text{C}(\text{O})\text{NR}^{13}\text{R}^{14}$ ,  $\text{NR}^{14}\text{C}(\text{O})\text{R}^{13}$ ,  $\text{C}(\text{O})\text{OM}$ ,  $\text{COR}^{13}$ ,  $\text{OR}^{18}$ ,  $\text{S}(\text{O})_n\text{NR}^{18}$ ,  $\text{NR}^{13}\text{R}^{18}$ ,



$\text{NR}^{18}\text{OR}^{14}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{P}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ , amino acid, peptide, polypeptide, and carbohydrate,

wherein alkyl, alkenyl, alkynyl, cycloalkyl, aryl, polyalkyl, heterocycle, heteroaryl, acyloxy, arylalkyl, haloalkyl, polyether, quaternary heterocycle, and quaternary heteroaryl can be further substituted with  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO}(\text{OR}^{16})\text{OR}^{17}$ ,  $\text{P}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ , or  $\text{C}(\text{O})\text{M}$ , and

wherein  $\text{R}^{18}$  is selected from the group consisting of acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl,

wherein acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl optionally are substituted with one or more substituents selected from the group consisting of  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_3\text{R}^9$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO}(\text{OR}^{16})\text{OR}^{17}$ , and  $\text{C}(\text{O})\text{OM}$ ,

wherein in  $\text{R}^x$ , one or more carbons are optionally replaced by O,  $\text{NR}^{13}$ ,  $\text{N}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^{13}\text{A}^-$ ,  $\text{PR}^{13}$ ,  $\text{P}(\text{O})\text{R}^{13}$ ,  $\text{P}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , phenylene, amino acid, peptide, polypeptide, carbohydrate, polyether, or polyalkyl,

wherein in said polyalkyl, phenylene, amino acid, peptide, polypeptide, and carbohydrate, one or more carbons are optionally replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{PR}^9$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ , or  $\text{P}(\text{O})\text{R}^9$ ;

wherein quaternary heterocycle and quaternary heteroaryl are optionally substituted with one or more groups selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo,  $\text{OR}^{13}$ ,  $\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S}(\text{O})\text{R}^{13}$ ,  $\text{SO}_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ , CN, OM,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{C}(\text{O})\text{NR}^{13}\text{R}^{14}$ ,  $\text{C}(\text{O})\text{OM}$ ,  $\text{COR}^{13}$ ,  $\text{P}(\text{O})\text{R}^{13}\text{R}^{14}$ ,  $\text{P}^+\text{R}^{13}\text{R}^{14}\text{R}^{15}\text{A}^-$ ,  $\text{P}(\text{OR}^{13})\text{OR}^{14}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , and  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,

provided that both R<sup>5</sup> and R<sup>6</sup> cannot be hydrogen, OH, or SH, and R<sup>5</sup> is OH, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>,

R<sup>4</sup>, R<sup>7</sup>, and R<sup>8</sup> cannot all be hydrogen;

provided that when R<sup>5</sup> or R<sup>6</sup> is phenyl, only one of R<sup>1</sup> or R<sup>2</sup> is H;

provided that when q=1 and R<sup>x</sup> is styryl, anilido, or anilinocarbonyl, only one of R<sup>5</sup> or R<sup>6</sup> is alkyl; or

a pharmaceutically acceptable salt, solvate, or prodrug thereof,

wherein said first and second amounts of said inhibitors together comprise an anti-hyperlipidemic condition effective amount, and

wherein said oral pharmaceutical composition is suitable for delivery of said anti-hyperlipidemic effective amount to the gastrointestinal tract of a patient by oral administration.

Claim 21 (new): The oral pharmaceutical composition of claim 20 wherein said oral pharmaceutical composition is suitable for delivery of said anti-hyperlipidemic effective amount to the small intestine of said patient.

Claim 22 (new): The oral pharmaceutical composition of claim 21 wherein said oral pharmaceutical composition is suitable for delivery of said anti-hyperlipidemic effective amount to the ileum of said patient.

Claim 23 (new): The oral pharmaceutical composition of claim 20 wherein said oral pharmaceutical composition is in a solid dosage form.

Claim 24 (new): The oral pharmaceutical composition of claim 23 wherein said solid dosage form is a slow erosion tablet or capsule.

Claim 25 (new): The oral pharmaceutical composition of claim 23 wherein said solid dosage form is a controlled release formulation having an enteric coating.

Claim 26 (new): The oral pharmaceutical composition of claim 25 wherein said enteric coating is selected from the group consisting of cellulose acetate phthalate, polyvinylacetate phthalate, hydroxypropylmethylcellulose phthalate, and an anionic polymer of methacrylic acid and methacrylic acid methyl ester.

Claim 27 (new): The oral pharmaceutical composition of claim 20 wherein said oral pharmaceutical composition provides prolonged or sustained release of said anti-hyperlipidemic amount.

Claim 28 (new): The oral pharmaceutical composition of claim 27 wherein said oral pharmaceutical composition is a pH sensitive release formulation.

Claim 29 (new): The oral pharmaceutical composition of claim 27 wherein said oral pharmaceutical composition is a bioadhesive formulation.

Claim 30 (new): The oral pharmaceutical composition of claim 27 wherein said anti-hyperlipidemic effective amount is released by enzymatic action.

Claim 31 (new): The oral pharmaceutical composition of claim 20 wherein said HMG Co-A reductase inhibitor is selected from the group consisting of pitavastatin, rosuvastatin, mevastatin, and cerivastatin.

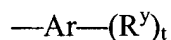
Claim 32 (new): The oral pharmaceutical composition of claim 20, wherein  $R^5$  and  $R^6$  are independently selected from the group consisting of H, aryl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl,

wherein said aryl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl can be substituted with one or more substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $SR^{13}$ ,  $S(O)R^{13}$ ,  $SO_2R^{13}$ ,  $SO_3R^{13}$ ,  $NR^{13}OR^{14}$ ,  $NR^{13}NR^{14}NR^{15}$ ,  $NO_2$ ,  $CO_2R^{13}$ , CN, OM,  $SO_2OM$ ,  $SO_2NR^{13}R^{14}$ ,  $C(O)NR^{13}R^{14}$ ,  $C(O)OM$ ,  $COR^{13}$ ,  $P(O)R^{13}R^{14}$ ,  $P^+R^{13}R^{14}R^{15}A^-$ ,  $P(OR^{13})OR^{14}$ ,  $S^+R^{13}R^{14}A^-$ , and  $N^+R^9R^{11}R^{12}A^-$ ,

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can optionally have one or more carbons replaced by O,  $NR^7$ ,  $N^+R^7R^8A^-$ , S, SO,  $SO_2$ ,  $S^+R^7A^-$ ,  $PR^7$ ,  $P(O)R^7$ ,  $P^+R^7R^8A^-$ , or phenylene,

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can be further substituted with one or more substituents independently selected from the group consisting of  $OR^7$ ,  $NR^7R^8$ ,  $SR^7$ ,  $S(O)R^7$ ,  $SO_2R^7$ ,  $CO_2R^7$ , CN, oxo,  $CONR^7R^8$ ,  $N^+R^7R^8R^9A^-$ , alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $P(O)R^7R^8$ ,  $P^+R^7R^8R^9A^-$  and  $P(O)(OR^7)OR^8$ .

Claim 33 (new): The oral pharmaceutical composition of claim 32, wherein  $R^5$  or  $R^6$  has the formula:

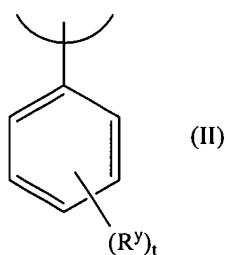


wherein:

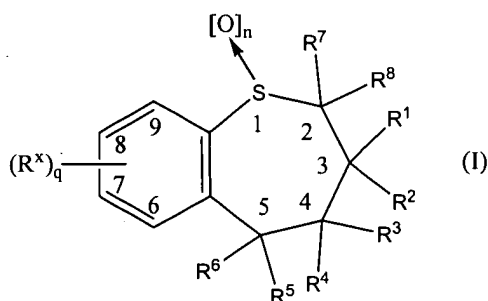
t is an integer from 0 to 5,

Ar is selected from the group consisting of phenyl, thiophenyl, pyridyl, piperazinyl, piperonyl, pyrrolyl, naphthyl, furanyl, anthracenyl, quinolinyl, isoquinolinyl, quinoxalinyl, imidazolyl, pyrazolyl, oxazolyl, isoxazolyl, pyrimidinyl, thiazolyl, triazolyl, isothiazolyl, indolyl, benzoimidazolyl, benzoxazolyl, benzothiazolyl, and benzoisothiazolyl; and  
one or more  $R^y$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $OR^9$ ,  $SR^9$ ,  $S(O)R^9$ ,  $SO_2R^9$  and  $SO_3R^9$ ,  
wherein said alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, and heteroaryl can be substituted with one or more substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $SR^{13}$ ,  $S(O)R^{13}$ ,  $SO_2R^{13}$ ,  $SO_3R^{13}$ ,  $NR^{13}OR^{14}$ ,  $NR^{13}NR^{14}R^{15}$ ,  $NO_2$ ,  $CO_2R^{13}$ , CN, OM,  $SO_2OM$ ,  $SO_2NR^{13}R^{14}$ ,  $C(O)NR^{13}R^{14}$ ,  $C(O)OM$ ,  $COR^{13}$ ,  $P(O)R^{13}R^{14}$ ,  $P^+R^{13}R^{14}R^{15}A^-$ ,  $P(OR^{13})OR^{14}$ ,  $S^+R^{13}R^{14}A^-$ , and  $N^+R^9R^{11}R^{12}A^-$ ,  
wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can be further substituted with one or more substituents independently selected from the group consisting of  $OR^7$ ,  $NR^7R^8$ ,  $SR^7$ ,  $S(O)R^7$ ,  $SO_2R^7$ ,  $SO_3R^7$ ,  $CO_2R^7$ , CN, oxo,  $CONR^7R^8$ ,  $N^+R^7R^8R^9A^-$ , alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $P(O)R^7R^8$ ,  $P^+R^7R^8R^9A^-$ , and  $P(O)(OR^7)OR^8$ ; and  
wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle and heteroaryl can optionally have one or more carbons replaced by O,  $NR^7$ ,  $N^+R^7R^8A^-$ , S, SO,  $SO_2$ ,  $S^-R^7A^-$ ,  $PR^7$ ,  $P(O)R^7$ ,  $P^+R^7R^8A^-$ , or phenylene.

Claim 34 (new): The oral pharmaceutical composition of claim 33, wherein  $R^5$  or  $R^6$  has the formula (II):



wherein said formula (I) is represented by:



wherein alkyl, alkenyl, alkynyl, haloalkyl, alkylaryl, arylalkyl, alkoxy, alkoxyalkyl, dialkylamino, alkylthio, (polyalkyl)aryl, and cycloalkyl optionally are substituted

with one or more substituents selected from the group consisting of  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{R}^w\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{R}^{11}\text{A}^-$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ ,  $\text{CO}_2\text{R}^9$ ,  $\text{CN}$ , halogen, oxo, and  $\text{CONR}^9\text{R}^{10}$ ,  
wherein alkyl, alkenyl, alkynyl, alkylaryl, alkoxy, alkoxyalkyl, (polyalkyl)aryl, and cycloalkyl optionally have one or more carbons replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ , or phenylene,  
wherein  $\text{R}^9$ ,  $\text{R}^{10}$ , and  $\text{R}^w$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, acyl, heterocycle, heteroaryl, ammoniumalkyl, arylalkyl, and alkylammoniumalkyl; or  
 $\text{R}^1$  and  $\text{R}^2$  taken together with the carbon to which they are attached form  $\text{C}_3\text{-C}_{10}$  cycloalkylidene;  
 $\text{R}^3$  and  $\text{R}^4$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, alkoxy, aryl, heterocycle, heteroaryl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ , and  $\text{SO}_3\text{R}^9$ , wherein  $\text{R}^9$  and  $\text{R}^{10}$  are as defined above; or  
 $\text{R}^3$  and  $\text{R}^4$  together form  $=\text{O}$ ,  $=\text{NOR}^{11}$ ,  $=\text{S}$ ,  $=\text{NNR}^{11}\text{R}^{12}$ ,  $=\text{NR}^9$ , or  $=\text{CR}^{11}\text{R}^{12}$ , wherein  $\text{R}^{11}$  and  $\text{R}^{12}$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, arylalkyl, alkenylalkyl, alkynylalkyl, heterocycle, heteroaryl, carboxyalkyl, carboalkoxyalkyl, cycloalkyl, cyanoalkyl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ ,  $\text{CO}_2\text{R}^9$ ,  $\text{CN}$ , halogen, oxo, and  $\text{CONR}^9\text{R}^{10}$ , wherein  $\text{R}^9$  and  $\text{R}^{10}$  are as defined above, provided that both  $\text{R}^3$  and  $\text{R}^4$  cannot be OH,  $\text{NH}_2$ , or SH, or  
 $\text{R}^{11}$  and  $\text{R}^{12}$  together with the nitrogen or carbon atom to which they are attached form a cyclic ring;  
 $\text{R}^5$  and  $\text{R}^6$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ , and  $\text{SO}_3\text{R}^9$ ,  
wherein alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, and quaternary heteroaryl can be substituted with one or more

substituents independently selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl, halogen, oxo,  $\text{OR}^{13}$ ,  $\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S(O)R}^{13}$ ,  $\text{SO}_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ ,  $\text{CN}$ ,  $\text{OM}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{C(O)NR}^{13}\text{R}^{14}$ ,  $\text{C(O)OM}$ ,  $\text{COR}^{13}$ ,  $\text{P(O)R}^{13}\text{R}^{14}$ ,  $\text{P}^+\text{R}^{13}\text{R}^{14}\text{R}^{15}\text{A}^-$ ,  $\text{P(OR}^{13})\text{OR}^{14}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ , and  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,

wherein:

$\text{A}^-$  is a pharmaceutically acceptable anion and  $\text{M}$  is a pharmaceutically acceptable cation, said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl can be further substituted with one or more substituents selected from the group consisting of  $\text{OR}^7$ ,  $\text{NR}^7\text{R}^8$ ,  $\text{SR}^7$ ,  $\text{S(O)R}^7$ ,  $\text{SO}_2\text{R}^7$ ,  $\text{SO}_3\text{R}^7$ ,  $\text{CO}_2\text{R}^7$ ,  $\text{CN}$ , oxo,  $\text{CONR}^7\text{R}^8$ ,  $\text{N}^+\text{R}^7\text{R}^8\text{R}^9\text{A}^-$ , alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, quaternary heterocycle, quaternary heteroaryl,  $\text{P(O)R}^7\text{R}^8$ ,  $\text{P}^+\text{R}^7\text{R}^8\text{R}^9\text{A}^-$ , and  $\text{P(O)(OR}^7)\text{OR}^8$  and

wherein said alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, and heteroaryl, can optionally have one or more carbons replaced by O,  $\text{NR}^7$ ,  $\text{N}^+\text{R}^7\text{R}^8\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^7\text{A}^-$ ,  $\text{PR}^7$ ,  $\text{P(O)R}^7$ ,  $\text{P}^+\text{R}^7\text{R}^8\text{A}^-$ , or phenylene, and  $\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, polyalkyl, aryl, arylalkyl, cycloalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl, and quaternary heteroarylalkyl,

wherein alkyl, alkenyl, alkynyl, arylalkyl, heterocycle, heteroaryl, and polyalkyl optionally have one or more carbons replaced by O,  $\text{NR}^9$ ,  $\text{N}^+\text{R}^9\text{R}^{10}\text{A}^-$ , S, SO,  $\text{SO}_2$ ,  $\text{S}^+\text{R}^9\text{A}^-$ ,  $\text{PR}^9$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{A}^-$ ,  $\text{P(O)R}^9$ , phenylene, carbohydrate, amino acid, peptide, or polypeptide, and

$\text{R}^{13}$ ,  $\text{R}^{14}$ , and  $\text{R}^{15}$  are optionally substituted with one or more groups selected from the group consisting of sulfoalkyl, heterocycle, heteroaryl, quaternary heterocycle, quaternary heteroaryl,  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S(O)R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ ,



oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO}(\text{OR}^{16})\text{OR}^{17}$ ,  $\text{P}^+\text{R}^9\text{R}^{10}\text{R}^{11}\text{A}^-$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ , and  $\text{C}(\text{O})\text{OM}$ ,  
wherein  $\text{R}^{16}$  and  $\text{R}^{17}$  are independently selected from the substituents constituting  $\text{R}^9$  and  $\text{M}$ ; or  
 $\text{R}^{14}$  and  $\text{R}^{15}$ , together with the nitrogen atom to which they are attached, form a cyclic ring;  
 $\text{R}^7$  and  $\text{R}^8$  are independently selected from the group consisting of hydrogen and alkyl;  
and  
one or more  $\text{R}^x$  are independently selected from the group consisting of H, alkyl, alkenyl, alkynyl, polyalkyl, acyloxy, aryl, arylalkyl, halogen, haloalkyl, cycloalkyl, heterocycle, heteroaryl, polyether, quaternary heterocycle, quaternary heteroaryl,  $\text{OR}^{13}$ ,  $\text{NR}^{13}\text{R}^{14}$ ,  $\text{SR}^{13}$ ,  $\text{S}(\text{O})\text{R}^{13}$ ,  $\text{S}(\text{O})_2\text{R}^{13}$ ,  $\text{SO}_3\text{R}^{13}$ ,  $\text{S}^+\text{R}^{13}\text{R}^{14}\text{A}^-$ ,  $\text{NR}^{13}\text{OR}^{14}$ ,  $\text{NR}^{13}\text{NR}^{14}\text{R}^{15}$ ,  $\text{NO}_2$ ,  $\text{CO}_2\text{R}^{13}$ , CN, OM,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^{13}\text{R}^{14}$ ,  $\text{NR}^{14}\text{C}(\text{O})\text{R}^{13}$ ,  $\text{C}(\text{O})\text{NR}^{13}\text{R}^{14}$ ,  $\text{NR}^{14}\text{C}(\text{O})\text{R}^{13}$ ,  $\text{C}(\text{O})\text{OM}$ ,  $\text{COR}^{13}$ ,  $\text{OR}^{18}$ ,  $\text{S}(\text{O})_n\text{NR}^{18}$ ,  $\text{NR}^{13}\text{R}^{18}$ ,  $\text{NR}^{18}\text{OR}^{14}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{P}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ , amino acid, peptide, polypeptide, and carbohydrate,  
wherein alkyl, alkenyl, alkynyl, cycloalkyl, aryl, polyalkyl, heterocycle, heteroaryl, acyloxy, arylalkyl, haloalkyl, polyether, quaternary heterocycle, and quaternary heteroaryl can be further substituted with  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,  $\text{S}(\text{O})\text{R}^9$ ,  $\text{SO}_2\text{R}^9$ ,  $\text{SO}_3\text{R}^9$ , oxo,  $\text{CO}_2\text{R}^9$ , CN, halogen,  $\text{CONR}^9\text{R}^{10}$ ,  $\text{SO}_2\text{OM}$ ,  $\text{SO}_2\text{NR}^9\text{R}^{10}$ ,  $\text{PO}(\text{OR}^{16})\text{OR}^{17}$ ,  $\text{P}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{S}^+\text{R}^9\text{R}^{10}\text{A}^-$ , or  $\text{C}(\text{O})\text{M}$ , and  
wherein  $\text{R}^{18}$  is selected from the group consisting of acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl,  
wherein acyl, arylalkoxycarbonyl, arylalkyl, heterocycle, heteroaryl, alkyl, quaternary heterocycle, and quaternary heteroaryl optionally are substituted with one or more substituents selected from the group consisting of  $\text{OR}^9$ ,  $\text{NR}^9\text{R}^{10}$ ,  $\text{N}^+\text{R}^9\text{R}^{11}\text{R}^{12}\text{A}^-$ ,  $\text{SR}^9$ ,

$S(O)R^9$ ,  $SO_2R^9$ ,  $SO_3R^9$ , oxo,  $CO_2R^9$ , CN, halogen,  $CONR^9R^{10}$ ,  $SO_3R^9$ ,  $SO_2OM$ ,  $SO_2NR^9R^{10}$ ,  $PO(OR^{16})OR^{17}$ , and  $C(O)OM$ ,  
wherein in  $R^x$ , one or more carbons are optionally replaced by O,  $NR^{13}$ ,  $N^+R^{13}R^{14}A^-$ , S, SO,  $SO_2$ ,  $S^+R^{13}A^-$ ,  $PR^{13}$ ,  $P(O)R^{13}$ ,  $P^+R^{13}R^{14}A^-$ , phenylene, amino acid, peptide, polypeptide, carbohydrate, polyether, or polyalkyl,  
wherein in said polyalkyl, phenylene, amino acid, peptide, polypeptide, and carbohydrate, one or more carbons are optionally replaced by O,  $NR^9$ ,  $N^+R^9R^{10}A^-$ , S, SO,  $SO_2$ ,  $S^+R^9A^-$ ,  $PR^9$ ,  $P^+R^9R^{10}A^-$ , or  $P(O)R^9$ ;  
wherein quaternary heterocycle and quaternary heteroaryl are optionally substituted with one or more groups selected from the group consisting of alkyl, alkenyl, alkynyl, polyalkyl, polyether, aryl, haloalkyl, cycloalkyl, heterocycle, heteroaryl, arylalkyl, halogen, oxo,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $SR^{13}$ ,  $S(O)R^{13}$ ,  $SO_2R^{13}$ ,  $SO_3R^{13}$ ,  $NR^{13}OR^{14}$ ,  $NR^{13}NR^{14}R^{15}$ ,  $NO_2$ ,  $CO_2R^{13}$ , CN, OM,  $SO_2OM$ ,  $SO_2NR^{13}R^{14}$ ,  $C(O)NR^{13}R^{14}$ ,  $C(O)OM$ ,  $COR^{13}$ ,  $P(O)R^{13}R^{14}$ ,  $P^+R^{13}R^{14}R^{15}A^-$ ,  $P(OR^{13})OR^{14}$ ,  $S^+R^{13}R^{14}A^-$ , and  $N^+R^9R^{11}R^{12}A^-$ ,  
provided that both  $R^5$  and  $R^6$  cannot be hydrogen, OH, or SH, and  $R^5$  is OH,  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^7$ , and  $R^8$  cannot all be hydrogen;  
provided that when  $R^5$  or  $R^6$  is phenyl, only one of  $R^1$  or  $R^2$  is H;  
provided that when  $q=1$  and  $R^x$  is styryl, anilido, or anilinocarbonyl, only one of  $R^5$  or  $R^6$  is alkyl; or  
a pharmaceutically acceptable salt, solvate, or prodrug thereof,  
wherein said first and second amounts of said inhibitors together comprise an anti-hyperlipidemic condition effective amount, and  
wherein said pharmaceutical composition is suitable for delivery of said anti-hyperlipidemic effective amount to the gastrointestinal tract of said patient by oral administration.

Claim 36 (new): The method of claim 35 wherein said pharmaceutical composition is suitable for delivery of said anti-hyperlipidemic effective amount to the small intestine of said patient.

Claim 37 (new): The method of claim 36 wherein said pharmaceutical composition is suitable for delivery of said anti-hyperlipidemic effective amount to the ileum of said patient.

Claim 38 (new): The method of claim 35 wherein said pharmaceutical composition is in a solid dosage form.

Claim 39 (new): The method of claim 38 wherein said solid dosage form is a slow erosion tablet or capsule.

Claim 40 (new): The method of claim 38 wherein said solid dosage form is a controlled release formulation having an enteric coating.

Claim 41 (new): The method of claim 40 wherein said enteric coating is selected from the group consisting of cellulose acetate phthalate, polyvinylacetate phthalate, hydroxypropylmethylcellulose phthalate, and an anionic polymer of methacrylic acid and methacrylic acid methyl ester.

Claim 42 (new): The method of claim 35 wherein said pharmaceutical composition provides prolonged or sustained release of said anti-hyperlipidemic amount.

Claim 43 (new): The method of claim 42 wherein said pharmaceutical composition is a pH sensitive release formulation.

Claim 44 (new): The method of claim 42 wherein said pharmaceutical composition is a bioadhesive formulation.

Claim 45 (new): The method of claim 42 wherein said anti-hyperlipidemic effective amount is released by enzymatic action.

Claim 46 (new): The method claim 35 wherein said HMG Co-A reductase inhibitor is selected from the group consisting of pitavastatin, rosuvastatin, mevastatin, and cerivastatin.